Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1088982	04/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc	3515 Murray St, Marinette, WI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the regional manager, the laboratory did not document the testing of the hematoxylin and eosin (H&E) stain for intended reactivity for one of eight testing days in the first three months of 2021. Findings include: 1. Review of the 'Mohs Patient Log' showed testing was performed on eight days from January through March 2021, including February 25, 2021. 2. Comparison of the 'Mohs Patient Log' with the 'Quality Control Assessment of Mohs Tissue Staining Procedure' log showed no evidence that the surgeon evaluated the quality of the H&E stain on February 25, 2021 when staff stained tissue samples using H&E stain. 3. Interview with the regional manager (staff A) on April 6, 2021 at 3:15 PM confirmed the surgeon evaluated H&E stained patient tissue samples on February 25, 2021 and did not document the stain quality for that day of testing.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records from 2020 and 2021 and interview with the regional manager, the laboratory director did not ensure the team leader's review of records was timely and sufficient to identify failures in quality as they occur. Findings include: 1. Review of Cryostat maintenance records from February 2020 through March 2021 showed the team leader signed and dated all records on March 25, 2021. 2. Review of the '2021 Room Temp/Humidity' Log showed the team leader signed the log on March 25, 2021. The instructions on the log direct personnel to record the room temperature each day the cryostat is in use. The log included no evidence the team leader had identified that staff did not document the temperature and humidity on February 25, 2021 when the laboratory used the cryostat. 3. Interview with the regional manager (staff A) on April 6, 2021 at 3:15 PM confirmed the review of records did not identify that the laboratory had not documented quality assessment measures on February 25, 2021, and confirmed the delayed review of records would not allow identification of failures in quality as they occur.